Remarks

Claims 1-30, 32, and 34-61 are pending in the application. Claims 1-30, 32, and 34-61 stand rejected. Claims 1, 2, 32, 34, 35, and 54 are amended as above. No new claims have been added. Support for the amendment to claims 1, 2, 32, 34, 35, and 54 can be found on page 4, lines 3-5. Applicant submits that no new matter has been added by these amendments. Applicant respectfully requests reexamination and reconsideration of the case, as amended. Each of the rejections levied in the Office Action is addressed individually below.

I. **Rejections under 35 U.S.C. § 103**. Claims 1-30, 32, 34-35, 41-46, and 55-61 have been rejected by the Examiner under 35 U.S.C. § 103(a) as being unpatentable over Cariapa *et al.* (U.S. Patent 5,437,610) in view of Waldridge (U.S. Patent 6,179,796). Examiner states that Cariapa teaches "a method including attaching a compression device to a body part of a patient suffering from a disease characterized by low blood flow . . . and applying graded sequential compression . . . using the compression apparatus." The Examiner further states that "Cariapa does not teach maximum pressure in the claimed range, however, Waldridge teaches an analogous device used for similar treatment, and discloses that pressures up to 255 mm Hg can be used, which fall within the claimed range of the applicant," and finally concludes that "it would have been obvious to one having ordinary skill in the art to provide maximum pressure in the claimed ranges." Applicant disagrees.

The Examiner is incorrect with respect to what Cariapa teaches. Cariapa teaches an apparatus for treating lymphedema, not a method for treating a disease characterized by low blood flow. Cariapa's device works to move lymph fluid from the extracellular space back into the vasculature by simulating the milking action that normally occurs during muscle action. In contrast, the present invention promotes angiogenesis and wound healing. The inventive system causes changes in the shear stress experienced by the vascular endothelial cells leading to the production of pro-angiogenic factors and other growth factors. These factors promote to angiogenesis and wound healing in the patient being treated. Applicant has amended independent claims 1, 2, 32, 34, 35, and 54 to clarify this feature of the claimed invention.

Applicant, therefore, respectfully submits that the amended claims are patentable over Cariapa even in view of Waldridge as discussed below.

Even if Cariapa is combined with Waldridge, there still is no teaching to suggest the use of external, graded sequential compression at the recited maximum pressures to treat diseases characterized by low blood flow. Waldridge, like Cariapa, is also limited to the treatment of lymphedema. Even though Waldridge may teach maximum pressures up to 255 mm Hg, it does not teach the use of the system in the treatment of diseases characterized by low blood flow by inducing angiogenesis. Typically, systems for reducing edema or preventing deep vein thromboses (DVTs) use pressures ranging from 20-50 mm Hg, as evidenced by column 6, lines 59-60 of Waldridge which states that the "therapeutic pressure is between 20 mmHg and 45 mmHg." The pressures needed in the claimed invention are higher and range from 75 mmHg to 300 mmHg because the inventive system changes the shear stress experienced by the endothelial cells of the patient. Given the different purposes of the claimed invention versus the systems of Cariapa and Waldridge, one of ordinary skill in this art would not look to these references for determining parameters such as maximum pressure. Therefore, these references, even if combined, do not render the claimed invention obvious because one of ordinary skill in this art would not look to these references for guidance because of the disparate purposes of the two systems.

Specifically in regard to claim 2, which recites a method of promoting wound healing, the Examiner acknowledges that "Cariapa does not explicitly disclose a method of promoting wound healing", but asserts "however the use of compression to facilitate wound healing is well known in the art and would have been obvious to the skilled artisan." Applicant disagrees. The method of treating lymphedema described by Cariapa is sufficiently different from the inventive method of treating wound healing that the Examiner cannot rely on such a conclusory statement as above without evidence from a reference. The Examiner is therefore, requested to remove this rejection of claim 2 or provide evidence that the use of compression to facilitate wound healing is well known in the art.

In regard to claims 3-8, 12, and 14-18, the Examiner states that since the Applicant has claimed function of performing those method steps, it would have been obvious to the skilled

artisan that the claimed effects would take place. This assertion is incorrect. The pressures required for inducing a change in the shear stress experienced by the vascular endothelial cells are different than those required for treating lymphedema as discussed above. Therefore, one cannot simply conclude the by performing the steps of the method the claimed effects would take place.

Further, claims 3 and 12 recite that the compression causes a reverse in the direction of the shear stress experienced by the endothelial cells or a reverse in the blood flow in the arterial vasculature of the patient. In the references cited, the compression used causes the lymph fluid to flow in the natural direction of lymph fluid flow (*i.e.*, distal to proximal), *e.g.*, up the arm toward the chest. In contrast, claims 3 and 12 recite reversing the natural flow of the blood in the vasculature. Therefore, the compression would cause the blood in these vessels to flow in the opposite direction of how blood normally flows. Neither of the references cited even mentions this possibility because this completely goes against what the authors of the references are trying to do. Reversing the flow of lymph fluid in an extremity would increase lymphedema in the extremity, not reduce it. Therefore, these references, in fact, teach away from what is claimed in claims 3 and 12. Since Cariapa and Waldridge teach away from what is taught in claims 3 and 12, claims 3 and 12 can clearly not be rendered obvious by the cited references even if they are combined.

With respect to claim 9-11 and 35, the Examiner states that "it would have been obvious to one of ordinary skill in the art to choose specific pressure ranges based on suitability for treatment of specific diseases." However, as discussed above, both Cariapa and Waldridge describe the treatment of lymphedema. They do not teach the treatment of a disease characterized by low blood flow. Therefore, these references cannot be used to render obvious the claimed invention because the maximum pressures needed in these two applications would be different, as discussed above. Cariapa and Waldridge cannot render obvious claims 9-11 and 35. Applicant requests that the rejection of these claims be withdrawn.

With respect to claim 26, neither Cariapa nor Waldridge teaches the use of a flexible band in the compression apparatus. Cariapa and Waldridge only use fluid filled bladders to exert pressure. The Examiner has not established a *prima facie* case of obviousness since the

discosures of the cited references do not teach or suggest all the elements of the claimed invention of claim 26. Applicant respectfully requests that the rejection be removed.

With respect to claims 27-30, Cariapa and Waldridge do not teach using their devices to treat cardiovascular diseases. They only teach using their devices to reduce lymphedema. The Examiner states that specific diseases such as vascular, coronary, artery, and cardiovascular diseases and diabetes are known to be treated by compression methods; however, the Examiner provides no evidence for such an assertion. The Examiner is respectfully requested to withdraw the rejection or provide evidence in support of this statement. Therefore, Cariapa even in combination with Waldridge cannot render obvious the claimed invention of claim 27-30.

With respect to claims 32 and 34, neither Cariapa nor Waldridge teaches the use of negative pressure. The Examiner is invited to point out the column and line numbers of a passage referring to the use of negative pressure in either of these references. Since neither teaches or even suggests the use of negative pressure, Applicant requests that the rejection of these claims be removed.

With respect to claim 55-61, the Examiner states that these "limitations drawn to specific speed ranges of waves, time periods for sequential compression, and pressure differences between the distal and proximal regions are considered matters of obvious design choice well within the knowledge of the skilled artisan." However, this is incorrect. The inventors have chosen these parameters based on the purpose of the invention, that is to promote wound healing and angiogenesis by inducing a change in the shear stress experienced by the endothelial cells of the patient. The cited art only teaches the treatment of lymphedema and does not teach or suggest changing the shear stress experienced by the endothelial cells. The art does not recognize the usefulness of changing the shear stress experienced by the endothelial cells. Therefore, one of ordinary skill in this art would not know to search for parameters which would lead to changing the shear stress. And nowhere do these references teach the wave speeds, time period of compression, and pressure differences recited in claims 55-61. Therefore, without such a teaching or suggestion, a skilled artisan even after reading the cited references would not choose the parameters as claimed. Applicant respectfully submits that these claims are therefore patentable over Cariapa and Waldridge.

Claims 35-39, 40, 44, and 47-53 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Zheng *et al.* (U.S. Patent 5,997,540) in view of Cariapa and Waldridge. The Examiner states that Zheng teaches a plurality of sequentially inflatable balloons, a blood oxygen detector, pulse oximeter, blood pressure detector, cooling means, and mounting means; however, as the Examiner admits, Zheng does not teach the specific maximum pressures and graded sequential pressures as claimed. The Examiner uses Cariapa to teach the desirability of graded sequential compression and Waldridge to teach the claimed pressure ranges. However, as discussed above, Cariapa and Waldridge even when combined fail to teach graded sequential compression with the maximum pressure ranges recited for use in treating diseases characterized by low blood flow by inducing a change in shear stress experienced by endothelial cells. Therefore, even if all three of these references were combined, there still would be no teaching for the graded sequential compression with the maximum pressure ranges cited as in the claimed invention. The Applicant, therefore, requests that the rejection be removed.

In view of the forgoing amendments and arguments, Applicant respectfully submits that the present case is now in condition for allowance. A Notice to that effect is requested.

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Respectfully submitted,

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